

**OSi**  
SPECIALTIES

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July 26, 1995



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August 1, 1995  
Document Processing Center (TS-790)  
Office of Pollution Prevention & Toxics  
U.S. Environmental Protection Agency  
1201 M Street SW  
Washington, DC 20460



Attn: TSCA 8(e) Coordinator  
Reference 8EHQ-0893-12242

**Contains No CBI**

Dear Sir or Madam:

OSi Specialties Incorporated (OSi) herewith submits the following information pursuant to TSCA Section 8(e), concerning preliminary unaudited information from a 4-hour acute inhalation study on Poly(oxy-1,2-ethanediyl), alpha-methyl-omega-[3-[1,3,3,3-tetramethyl-1-1-[(trimethylsilyl)oxy]disiloxanyl]propoxy]- (SILWET® L-77, CASRN 27306-78-1), a surfactant. A previous TSCA 8(e) submission has been made by OSi (August 27, 1993) and assigned file number 8EHQ-0893-12242. The information provided in this letter is based on the instructions regarding reportability of mortality data in the form of LD<sub>50</sub> or LC<sub>50</sub> stated in the EPA's TSCA Section 8(e) Reporting Guide. OSi received this information on July 10, 1995. This information is summarized as follows.

A study of L-77 in albino rats was conducted to determine the acute inhalation median lethal concentration (LC<sub>50</sub>) and evaluate potential adverse effects of the test material when administered as a single, four-hour, whole body exposure to rats. This study was used to select doses for a subsequent 9-day inhalation toxicity study. The actual mean concentrations of test material attained, as determined by gravimetric sampling, were 0.26, 1.1, and 2.0 mg/l. The preliminary unaudited findings from the study suggest that L-77 is toxic via inhalation. Seven of the thirty rats that were exposed died. Three female rats were found dead during the study, including one in the 1.1 mg/l group on day 5 and two in the 2 mg/l group on day 3. A total of four rats, one 1.1 mg/l male and three (two male, one female) in the 2 mg/l group, were euthanized for humane reasons. Therefore, overall mortality during the study was 0/10, 2/10, and 5/10 for the 0.26, 1.1, and 2 mg/l target groups.

The lethal concentration in 50% of the animals for a 4-hour exposure reported in this unaudited study is 2 mg/l. As indicated in EPA's 8(e) reporting guidelines, a 4-hour LC<sub>50</sub> inhalation dose greater than 0.5 mg/l and less than or equal to 2 mg/l is considered to be highly toxic. There were no clinical signs which were considered to be reportable under TSCA 8(e).

**PRODUCT SAFETY AND REGULATORY AFFAIRS**

Telephone: (304) 652-3211 Fax: (304) 652-1478  
OSi Specialties, Inc., P.O. Box 180, Sistersville, WV 26175

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A complete evaluation of the relevance of these preliminary, unaudited findings must await completion of the study. A full or partial copy of the audited report will be sent to the Agency, upon your request. We must comment that the commercial use of this material would never cause the product to be aerosoled as a neat material, but only as a 0.5 % solution in water.

While no assertion of confidentiality is made, the Agency is advised that the publication rights to this information are the property of OSi.

Please feel free to contact me with any questions at the address or phone number as shown on the letterhead.

Regards,



OSi Specialties, Inc.  
C. R. Thrash, Manager  
Product Safety and Regulatory Affairs

CRT:bs

cc: J. H. Cornell  
G. J. Murphy  
P. E. Austin  
J. J. Walsh  
A. M. Lanchak